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*Indian Standard*

# DISPOSABLE SURGICAL RUBBER GLOVES — SPECIFICATION

UDC 685·45 : 615·472·92

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

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Price Group 2

Rubber Sectional Committee, PCD 13

## FOREWORD

This Indian standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Rubber Products Sectional Committee had been approved by the Petroleum, Coal and Related Products Division Council.

Bureau of Indian Standards has already published IS 4148 : 1989 'Surgical rubber gloves — Specification ( *first revision* )' which prescribes the requirements for reusable surgical gloves. Disposable surgical gloves are now being increasingly used and large quantities of the same are exported. A request for formulation of this Indian Standard was received from Quality Development Centre, Export Inspetion Agency.

This standard covers two types of gloves, namely, those made from natural rubber cement or from synthetic rubber latex. The various tests prescribed are expected to ensure reasonable performance for their use. A suitable lubricant powder may be used in the packed gloves as agreed to between the purchaser and the supplier. This surface powder should be aseptically removed prior to undertaking operative procedures to minimize the risk of adverse tissue reaction.

In preparation of this standard assistance has been derived from following standards:

ASTM D 3577 : 1988 'Standard Specification for Rubber Surgical Gloves', issued by the American Society for Testing and Materials, USA; and

Doc ISO/TC 45/SC 4/WG 8 N 15 'Rubber-Gloves, Surgical, Single-use — Specification', issued by the International Organization for Standardization.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values ( *revised* )'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

# *Indian Standard*

# DISPOSABLE SURGICAL RUBBER GLOVES — SPECIFICATION

## 1 SCOPE

**1.1** This standard specifies requirements for packaged sterile gloves intended for use in surgical procedures. It is applicable to single use gloves which are worn once and then discarded.

**1.1.1** This standard does not apply to examination or procedure gloves.

**1.2** This specification is intended as a reference to the performance and safety of surgical rubber gloves. The safe and proper usage of surgical gloves and sterilization procedures with subsequent handling and storage procedures are beyond the scope of this standard.

## 2 REFERENCES

**2.1** The following Indian Standards are necessary adjuncts to this standard:

| *IS No.* | *Title* |
|---|---|
| 196 : 1966 | Atmospheric conditions for testing ( *first revision* ) |
| 3400 | Method of test for vulcanized rubbers: |
| ( Part 1 ) : 1987 | Tensile stress-strain properties ( *second revision* ) |
| ( Part 4 ) : 1987 | Accelerated ageing ( *second revision* ) |
| 7503 | Glossary of terms used in rubber industry: |
| ( Part 1 ) : 1988 | Basic terms ( *first revision* ) |
| ( Part 2 ) : 1988 | Definitions of additives ( *first revision* ) |
| ( Part 3 ) : 1988 | Definitions relating to properties and testing ( *first revision* ) |
| ( Part 4 ) : 1988 | Definitions relating to processing ( *first revision* ) |

## 3 TERMINOLOGY

**3.1** For the purpose of this standard, the definitions given in IS 7503 ( Parts 1 to 4 ) : 1988 shall apply.

## 4 TYPES

**4.1** Gloves shall be of two types.

**4.1.1** *Type 1* — Gloves compounded primarily from natural rubber latex.

**4.1.2** *Type 2* — Gloves compounded from a rubber cement or from synthetic rubber latex.

## 5 REQUIREMENTS

### 5.1 Materials

Gloves shall be manufactured from compounded natural rubber latex concentrate or synthetic latex or rubber solution. Any surface treatment, lubricant or powder to facilitate donning the gloves shall be one of approved safety and efficacy. The nature of the material shall be disclosed on request. Any surface treatment capable of being transferred must be bio-absorbable, non-toxic and non-pyrogenic. It must not be affected by different methods of sterilization. The minimum level should be used.

NOTE — Allergenic reaction; it is recognized that some individuals, may, over a period of time become sensitized to a particular rubber compound and require gloves of an alternative formulation.

### 5.2 General Characteristics and Dimensions

**5.2.1** *The Cuff*

The cuff of the glove shall be constructed in such a fashion that it is resistant to tear. The design of the cuff shall fit closely without being constrictive. The cuff shall not exhibit any tendency to roll back or ruckle while in use. The thickness of the cuff when measured using a gauge with a 5 mm diameter foot, shall not exceed 3 mm.

**5.2.2** *Dimensions*

The gloves shall comply with the dimensional requirements specified in Table 1.

**5.2.2.1** The length shall be expressed in millimetres as measured from the tip of the second finger to the outside edge of the cuff.

**5.2.2.2** The width of the palm shall be expressed in millimetres as measured at a level between the base of the index finger and the base of the thumb. Values of width per size other than listed shall meet the stated tolerance specified in Table 1.

**5.2.3** *Thickness*

The minimum thickness shall be expressed in millimetres as specified in Table 1 when using a dial micrometer and in the locations indicated on Fig. 1. For referee tests, cutting the glove is necessary to obtain single-thicknesss measurements.

### 5.3 Physical Properties

#### 5.3.1 *Tensile Strength and Elongation at Break*

The tensile strength and elongation at break for the rubber of the glove when tested as prescribed in IS 3400 ( Part 1 ) : 1987 using universal testing machine shall not be less than as specified in Table 2.

#### 5.3.2 *Accelerating Ageing*

The glove or suitable portion of glove, when subjected to accelerated ageing at a temperature of 70 ± 2°C for 168 h or 100 ± 2°C for 22 h in accordance with IS 3400 ( Part 4 ) : 1987 shall have tensile strength and elongation at break not less than as specified in Table 2.

### 5.4 Sterility Test

Testing for sterility shall be conducted in accordance with the latest edition of the Indian Pharmacopeia.

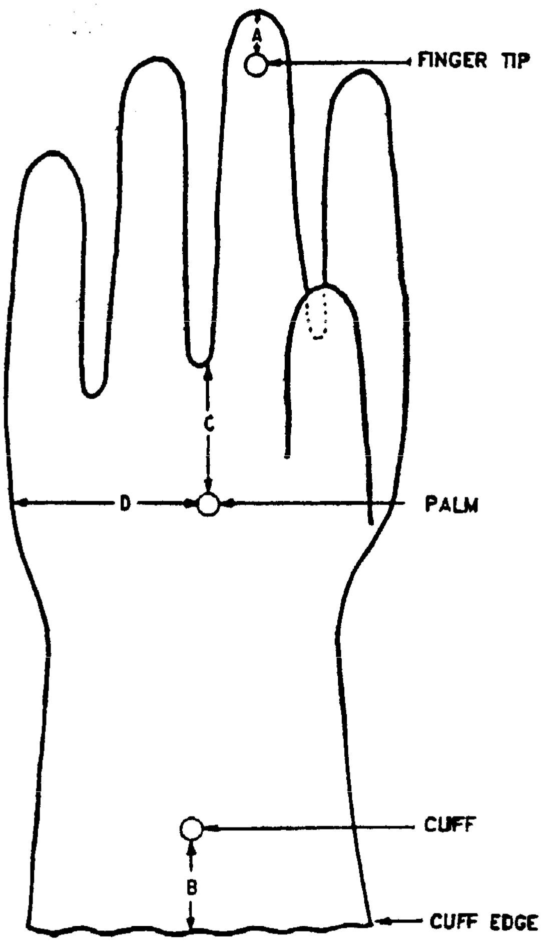
### 5.5 Airtight Test

Holes in the glove shall be detected by fastening the cuff to a circular mandrel, inflating with air to a gauge pressure of 1·5 kPa and immersing in water at room temperature to a depth of 200 ± 10 mm above the tip of the middle finger. The inflation pressure shall be ± 10 percent and the immersion time shall be 1·5 ± 0·5 minutes. Emergence of air bubbles from the glove constitutes an airtight failure. The mandrel shall have a diameter of 90 ± 1 mm and the minimum mass of 1·5 kg. The mandrel is bored for air passage and tapped to accept a suitable 90° pipe-to-hose elbow adaptor. The inflation apparatus consists of the following: pressure bulb with control valve, tubing, 0 to 5 kPa pressure gauge, hose tee, 90° elbow adaptor, water and fastener. The inflation apparatus shall be assembled by attaching three suitable lengths of tubing to the bore. Tubing from the tee leg is connected to the pressure bulb. Tubes from the other legs of the tee are connected to the pressure gauge and the mandrel.

## 6 TEST PIECES

Where test pieces are required they shall be taken from the palm or cuff of unused gloves avoiding textured areas, if possible.

For tensile strength and elongation at break, carry out all the tests on the material obtained from smooth portion of a glove. Use four dumb-bell test pieces for each test. Cut the dumb-bell in such a way so that the test length is parallel to the length of the glove. For accelerated ageing take representative sample of glove as such or a suitable test piece cut from the glove.



| Distance | mm |
|---|---|
| *A* | 13 ± 3 |
| *B* | 25 ± 5 |
| *C* | 33 ± 7 |
| *D** | 48 ± 9 |

*Dimension *D* to locate approximate centre of palm with respect to glove size.

FIG. 1 LOCATION OF THICKNESS MEASUREMENTS

## 7 STANDARD ATMOSPHERIC CONDITIONS FOR PHYSICAL TEST

The test specimen shall be conditioned to a moisture equilibrium in an atmosphere of 65 ± 5 percent relative humidity and 27 ± 2°C temperature ( *see* IS 196 : 1966 ) and if possible, tested in that atmosphere or soon after removal from the atmosphere.

## 8 PACKAGING AND MARKING

### 8.1 Packaging

Packaging shall be provided to maintain sterility after sterilization during shipping and storage and to permit opening without contamination of the gloves.

**Table 1 Dimensions and Tolerances**

( *Clauses* 5.2.2 *and* 5.2.3 )

| Designation | Size | | | | | | | | Tolerance |
|---|---|---|---|---|---|---|---|---|---|
| | 5½ | 6 | 6½ | 7 | 7½ | 8 | 8½ | 9 | |
| Length, mm | 245 | 265 | 265 | 265 | 265 | 265 | 265 | 265 | *Min* |
| Width, mm | 70 | 76 | 83 | 89 | 95 | 102 | 108 | 114 | ± 6 |
| Thickness, mm: | | | | | | | | | *Min* |
| Finger | | | | | 0·10 | | | | |
| Palm | | | | | 0·10 | | | | |
| Cuff | | | | | 0·10 | | | | |

**Table 2 Physical Requirements**

( *Clauses* 5.3.1 *and* 5.3.2 )

| Type | Before Ageing | | | After Accelerated Ageing | |
|---|---|---|---|---|---|
| | Tensile Strength MPa, *Min* | Ultimate Elongation Percent, *Min* | Stress at 500 Percent Elongation MPa, *Max* | Tensile Strength MPa, *Min* | Ultimate Elongation Percent, *Min* |
| (1) | (2) | (3) | (4) | (5) | (6) |
| I | 24 | 750 | 5·5 | 18 | 560 |
| II | 17 | 650 | 7·0 | 12 | 490 |

### 8.2 Marking

Each glove/package shall be legibly marked with the following particulars:

a) Indication of the source of manufacture;

b) Month and year of manufacture;

c) Gloves shall have an appropriate marking or be colour-coded to designate size;

d) Inner wrappers or wallets, if utilized, shall bear a size marking to be located on the outside of the wallet or wrapper;

e) Packages shall bear markings for the contents to include the glove size, instructions for opening, the legend "sterile", and a manufacturing lot number;

f) The outermost case shall be labelled on one or more end panels with the glove size, the legend "sterile", and a manufacturing lot number;

g) All levels of packaging shall conform to all appropriate government labelling regulations;

h) The expiry date marked as 'Use before...'; and

j) The words 'Use Once Only'.

**8.2.1** The product may also be marked suitably with the Standard Mark.

## 9 SAMPLING AND CRITERIA FOR CONFORMITY

**9.1** For the purpose of ascertaining the conformity of the gloves in a consignment to this specification, the scale of sampling and criteria for conformity shall be as prescribed in Annex A.

# ANNEX A

( *Clause* 9.1 )

## SAMPLING PLAN FOR SURGICAL RUBBER GLOVES

### A-1 SCALE OF SAMPLING

### A-1.1 Lot

All surgical gloves of the same type and size produced from a single mix or raw materials and processed exactly under identical conditions shall be grouped to constitute a lot.

**A-1.2** Each lot shall be examined separately for judging its conformity to the requirements of this specification. For this purpose, a number of gloves shall be selected at random from the lot. The number of gloves to be selected shall depend on the size of the lot and shall be in accordance with col 1 and 2 of Table 3.

**A-1.3** The gloves shall be selected from the lot at random. In order to ensure randomness of selection, random number tables shall be used. In case, random number tables are not available, the following procedure may be adopted:

> Starting from any item in the lot, count them in one order as 1,2,3 , up to *r* and so on, where *r* is the integral part of *N*/*n*, *N* being the number of items in the lot and *n* the number of items to be selected. Every *r*th item thus counted shall be withdrawn to constitute the sample.

## A-2 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

**A-2.1** All the gloves selected in **A-1.2** shall be first examined for the dimensional and size requirements. For this purpose the gloves shall be selected as per col 1 and 2 of Table 3. Any glove failing in this requirement shall be termed as defective. The lot shall be considered as conforming to these requirements, if the number of defectives do not exceed the corresponding acceptance number given in col 3 of Table 3, otherwise not.

**A-2.2** If the lot has been found satisfactory in **A-2.1**, it shall then be subjected to airtight and sterility tests. For this purpose, the sample size and acceptance number are given in col 4 and 5 of Table 3.

**A-2.3** The lot shall then be tested for physical properties. For this purpose, the sample size is given in col 6 of Table 3. The lot shall be considered as conforming to these requirements if there is no failure during the tests.

**A-2.3.1** The lot shall be declared as conforming to the requirements of the specification if **A.2.1**, **A-2.2** and **A-2.3** are satisfied.

**Table 3 Sample Sizes and Acceptance Numbers**

( *Clauses* A-1.2, A-2.1, A-2.2 *and* A-2.3 )

| Lot Size | For Dimensional Requirements | | For Airtight and Sterility Tests | | For Physical Properties |
|---|---|---|---|---|---|
| | Sample Size | Acceptance Number | Sample Size | Acceptance Number | Sample Size |
| (1) | (2) | (3) | (4) | (5) | (6) |
| Up to 25 | 5 | 0 | 3 | 0 | 2 |
| 26 to 50 | 8 | 0 | 5 | 0 | 3 |
| 51 to 100 | 13 | 0 | 8 | 0 | 3 |
| 101 to 300 | 20 | 1 | 13 | 0 | 5 |
| 301 to 500 | 32 | 2 | 13 | 0 | 5 |
| 501 to 1 000 | 50 | 3 | 20 | 1 | 5 |
| 1 001 and above | 80 | 5 | 32 | 2 | 8 |

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